Consultation on applications for six novel foods

Launch date: 17 December 2021

Respond by: 11 February 2022

This consultation will be of most interest to

- Manufacturers of infant and follow-on-formula and other food businesses wishing to use the novel foods (NFs) in the proposed use categories, such as food supplement manufacturers and distributors
- Enforcement Authorities, including Local Authorities, Port Health Authorities and District Councils
- Consumers of end use products including consumer groups concerned with infant formula and follow-on-formula and parents/carers of infants

Consultation subject and purpose

This consultation is to seek stakeholders' views, comments and feedback in relation to the regulated product applications considered in this document, which have been submitted for authorisation. We ask stakeholders to consider any relevant provisions of retained EU law and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors), including those that the Food Standards Agency (FSA) and Food Standards Scotland (FSS) have identified as relevant to these applications. This is stakeholders' opportunity for input on the advice given to Ministers to inform decision making.

The FSA/FSS opinions, and the views gathered through this consultation, will be considered and included alongside those of Officials of the Devolved Governments in Northern Ireland, Scotland and Wales and UK Government Departments other than the FSA to inform Ministers' decision making on whether to authorise the individual NFs for use in England, Scotland and Wales.

A parallel consultation is being published by FSS.

How to respond

Responses to this consultation should be sent to:
Email: RPconsultations@food.gov.uk
Name: Regulated Products Approvals Team
Division/Branch: Chemical Safety Policy Unit

Details of consultation

In accordance with Retained EU Regulation 2015/2283 on NFs, the NFs included in this consultation have been submitted for authorisation.

Six NFs have been submitted for authorisation in each nation of Great Britain (GB), where the decision on authorisation is made by the respective Ministers in England, Scotland and Wales. This is a function that was previously carried out at a European Union (EU) level. Since the end of the transition period, protection of public health in relation to the consumption of food and consumer interests in relation to food in the UK is the responsibility of FSA/FSS and the authorisation of regulated products is the responsibility of the relevant appropriate authority of each of the nations of GB.

In respect to Northern Ireland, EU Food Law on NFs continues to apply under the current terms of the Protocol on Ireland/Northern Ireland (NIP). This means NFs require authorisation under the EU's authorisation procedures before being placed on the market in Northern Ireland.

Each application is considered within a separate annex, including the regulated product ID number and title of the application (Ctrl+Click to follow link):

Introduction

The FSA and FSS have been working together to ensure that the high standard of food safety and consumer protection in the UK continues following the UK's exit from the EU.

Regulated product applications for the GB market, including NFs, are now subject to the UK's own risk analysis process, with FSA/FSS continuing to provide advice to Ministers on matters of food safety.

NFs are foods that have not been used for human consumption to a significant degree within the UK or EU before 15 May 1997. In order to place new NFs on the GB market, or to change the specifications or conditions of use of authorised NFs, applicants must submit an application in accordance with Retained EU Regulation 2015/2283. The applications included in this consultation are Article 10 authorisation applications.

Following consultation, the next step of the authorisation process is for relevant Ministers in England, Scotland and Wales to make decisions on authorisation (with Ministers in Northern Ireland kept informed), taking into account the FSA/FSS opinion, any relevant provisions of retained EU law and any other legitimate factors. Details of the individual NFs are given in the annexes. FSA/FSS advice to Ministers, subject to views gathered in the consultation, will be to authorise these NFs on the proposed terms as outlined in the FSA/FSS opinions.

In line with FSA/FSS' responsibility to provide advice to Ministers in respect of matters connected with food safety or other interests of consumers in relation to food (section 6, Food Standards Act 1999), we have identified factors which may inform Ministerial decision making. The outlines of these factors also take into account the impact of any decision ultimately made by Ministers, whether this is to authorise or not. Stakeholders are invited to use this opportunity to comment on these factors or highlight any additional factors that should be brought to the attention of Ministers before a final decision is made.

Ministers in all four nations have provisionally agreed to a provisional common framework for Food and Feed Safety and Hygiene. This consultation has been developed under the commitments to collaborative four-nation working set out in this framework. As such, this consultation has been developed through cross-government forums with the Department of Health and Social Care (DHSC), Welsh Government and Scottish Government. The content of this consultation represents the views of FSA/FSS and the factors that FSA/FSS has identified as relevant to these applications. Final advice will be agreed on a four-nation basis before being presented to Ministers.

Impacts

As part of the risk analysis process, FSA/FSS has assessed the impacts that would result from authorisation of these NFs, should Ministers decide to authorise. Our collective assessment of the proposals did not identify any significant impacts. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e., Local Authority Delivery, Health, Environment, Growth, Innovation, Trade, Competition, Consumer Interests or Small and Micro Businesses). The authorisation of these products should generally result in greater market competition supporting growth and innovation in the sector.

Under the provisional common framework for Food and Feed Safety and Hygiene, Northern Ireland continues to have full participation in the risk analysis processes concerning food and feed safety. This reflects Northern Ireland's integral role within the UK and ensures that any decision made fully considers the potential impacts on the whole of the UK. The NFs included within this consultation are authorised for use in Northern Ireland, in line with legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

Engagement and Consultation Process

Details of all validated applications for regulated products are published on the Register of Regulated Product Applications on the Food Standards Agency Website.

Stakeholders are invited to consider the questions posed below in relation to any relevant provisions of retained EU law and other legitimate factors.

Following the consultation process responses will be published and made available to stakeholders and Ministers.

Questions asked in this consultation:

1. Do you have any concerns on the safety of the NFs which have not been considered below with respect to the intended consumers, stakeholders or impacts?
2. Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual NFs, and if in favour of authorisation, the terms on which the NFs are authorised (as outlined in the FSA/FSS opinions)?
3. Are there any other factors that should be considered by Ministers that have not been highlighted?
4. Do you have any other feedback?

Responses

This consultation will run for 8 weeks. Responses are required by close 11 February 2022. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents) and in which nation you are based.

All responses to this consultation will be published by the Food Standards Agency within 12 weeks of the consultation closing.

Please indicate which application(s)/product(s) you are responding about by using the following subject line for your response:

Response to [insert RP number(s)] NF consultation.

Please send response to RPconsultations@food.gov.uk

For information on how the FSA handles your personal data, please refer to the Consultation privacy notice.

Responses will be shared with FSS.

Further information

If you require a more accessible format of this document, please send details to the named contact for responses to this consultation and your request will be considered.

This consultation has been prepared in accordance with HM Government consultation principles.

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

Shaun Jacobs
Novel Foods Policy Advisor
Chemical Safety Policy Unit

Annex A: RP8 – 3’-Sialyllactose (3’-SL) (new)

Background

This application was submitted as set out in Retained EU Regulation 2015/2283. The application was submitted for 3’-sialyllactose sodium salt (3’-SL), which is obtained from fermentation with a genetically modified (GM) strain of *Escherichia coli* K 12 DH1 (no GM material present in end product) and is isolated as a purified ingredient in the sodium salt form. 3’-SL is a trisaccharide made from glucose, galactose and N-acetylneuraminic acid (NANA, also known as “sialic acid”). The manufactured 3’-SL is identical in structure to the same molecule that is present in human milk and is referred to as human-identical milk oligosaccharide (HiMO).

The applicant has requested data protection (DP) and confidentiality of certain scientific data and evidence included in their application, as permitted in Article 26 and Article 23 of Retained EU Regulation 2015/2283. An applicant’s request for DP and confidentiality can be granted as part of the authorisation, this is subject to a data protection period of 5 years as stated in Retained EU Regulation 2015/2283 – such that only the applicant is able to market this NF during that time, unless a subsequent application is made without reference to the propriety scientific data, or with the agreement of the applicant.

Proposed terms for entry to the list of authorised novel foods

The proposed terms for entry to the list of authorised novel foods are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms and is not liable to have an effect on human health.

The designation of the NF on the labelling of the foodstuffs containing it shall be “3'-Sialyllactose sodium salt”.

The labelling of food supplements as defined by Directive 2002/46 containing 3'-Sialyllactose sodium salt shall bear a statement that they should not be consumed:

a. if foods containing added 3'-Sialyllactose sodium salt are consumed the same day;

b. by infants and young children.

Any relevant provisions of retained EU law

FSA/FSS has not identified any relevant provisions of retained EU law that would impact authorisation for this product.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the consumer interests (outlined below) and recent EU authorisation of this NF. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Consumer interests: Consumers have shown a preference for labelling of GM products however this product would not be classed as GM as there is no GM material present in the end product. The production process uses a GM production microorganism as a processing aid. The GM microorganism is derived from a parental *E. coli* K-12 DH1 strain which is non-pathogenic. *E. coli* K-12 has been assessed as a safe, non-pathogenic or toxigenic microorganism which is widely used for biotechnological applications. Five batches of the NF were tested by the applicant to demonstrate the absence of the production microorganism in the final product and to demonstrate the microbiological safety of the final product.

This NF is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex B: RP9 – 6′-Sialyllactose (6′-SL) (new)

Background

This application was submitted as set out in Retained EU Regulation 2015/2283. The application was submitted for 6'-sialyllactose sodium salt ("6'-SL"), the NF is produced by fermentation with a genetically modified strain of *Escherichia coli* K-12 DH1 (no GM material present in end product) and is isolated as a purified ingredient in the sodium salt form. 6'-SL is a trisaccharide made from glucose, galactose and N-acetylneuraminic acid (NANA, also known as "sialic acid"). Glucose and galactose comprise the milk sugar lactose and NANA is an acidic monosaccharide (approved as a NF ingredient in its own right for use in a variety of foods including infant and follow-on formula).

The manufactured 6'-SL is identical in structure to the same molecule that is present in human milk and is referred to as human-identical milk oligosaccharide (HiMO). There are 2 naturally occurring sialyllactoses, namely 6'-SL and 3'-sialyllactose (3'-SL), which are regio-isomers (i.e. the NANA moiety is connected to another position of lactose).

The applicant has requested DP and confidentiality of certain scientific data and evidence included in their application, as permitted in Article 26 and Article 23 of Retained EU Regulation 2015/2283. An applicant's request for DP and confidentiality can be granted as part of the authorisation, this is subject to a data protection period of 5 years as stated in Retained EU Regulation 2015/2283 – such that only the applicant is able to market this NF during that time, unless a subsequent application is made without reference to the propriety scientific data, or with the agreement of the applicant.

Proposed terms for entry to the list of authorised novel foods

The proposed terms for entry to the list of authorised novel foods are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms and is not liable to have an effect on human health.

The designation of the NF on the labelling of the foodstuffs containing it shall be "6'-Sialyllactose sodium salt".

In line with the conditions of use of food supplements containing 6'-SL sodium salt as proposed by the applicant and assessed by FSA/FSS, it is necessary to inform consumers with an appropriate label that food supplements containing 6'-SL sodium salt

should not be consumed the same day, if other foods with added 6'-SL sodium salt are consumed the same day.

Food supplements are not intended to be used if other foods with added NF or breast milk are consumed on the same day.

The labelling of food supplements containing 6'-Sialyllactose (6'-SL) sodium salt shall bear a statement that they should not be consumed:

a. if foods containing added 6'-Sialyllactose sodium salt are consumed on the same day.

b. by infants and young children.

Any relevant provisions of retained EU law

FSA/FSS has not identified any relevant provisions of retained EU law that would impact authorisation for this product.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the consumer interests (outlined below) and recent EU authorisation of this NF. The other legitimate

factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Consumer interests: Consumers have shown a preference for labelling of GM products however this product would not be classed as GM as there is no GM material present in the end product. The production process uses a GM production microorganism as a processing aid. The GM microorganism is derived from a parental *E. coli* K-12 DH1 strain which is non-pathogenic. *E. coli* K-12 has been assessed as a safe, non-pathogenic or toxigenic microorganism which is widely used for biotechnological applications. Five batches of the NF were tested by the applicant to demonstrate the absence of the production microorganism in the final product and to demonstrate the microbiological safety of the final product.

This NF is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex C: RP14 – 2’-Fucosyllactose / difucosyllactose mixture (“2’-FL/DFL mixture”) (extension of use for current authorisation)

Background

The applicant has applied for an extension of use of the permitted NF 2’-Fucosyllactose/difucosyllactose (2’-FL/DFL) mixture to also allow its use in milk-based drinks and similar products intended for young children. The applicant has also sought to include additional clarity in the identity and specification for 2’-FL/DFL mixture. Specifically, the applicant proposes to remove the method of drying and to include 3-fucosyllactose in the assay value for key oligosaccharides (naturally present in human breast milk) rather than with the “sum of other carbohydrates”.

The applicant has requested confidentiality of certain scientific information included in their application, as permitted in Article 23 of Retained EU Regulation 2015/2283.

Proposed terms for entry to the list of authorised novel foods

The proposed terms for entry to the list of authorised novel foods are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms and is not liable to have an effect on human health.

Any relevant provisions of retained EU law

FSA/FSS has not identified any relevant provisions of retained EU law that would impact authorisation for the extension of use of this product.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are

acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the consumer interests (outlined below) and recent EU authorisation of this NF. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Consumer interests: Consumers have shown a preference for labelling of GM products however this product would not be classed as GM as there is no GM material present in the end product. The production process uses a GM production microorganism as a processing aid. The GM microorganism is derived from a parental *E. coli* K-12 DH1 strain which is non-pathogenic. *E. coli* K-12 has been assessed as a safe, non-pathogenic or toxigenic microorganism which is widely used for biotechnological applications. Five batches of the NF were tested by the applicant to demonstrate the absence of the production microorganism in the final product and to demonstrate the microbiological safety of the final product.

This NF is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex D: RP87 – DHA-rich algal oil from *Schizochytrium* sp strain WZU477 (extension of use for current authorisation)

Background

This application was submitted as set out in Retained EU Regulation 2015/2283. The application was submitted for an extension of use of docosahexaenoic acid (DHA)-rich algal oil sourced from the marine microalgae *Schizochytrium* sp. to include strain WZU477 as a NF ingredient for use in infant and follow-on formula (as defined in Retained EU Regulation 609/2013) in the list of authorised novel foods as an alternative source of fatty acids presently permitted in these products. The applicant proposes to extend the approval of DHA-rich algal oil sourced from *Schizochytrium* sp. to include strain WZU477 as a NF ingredient for use in fruit/vegetable puree with a maximum DHA content of 100 mg/100 g. No other changes to the existing specifications are proposed.

The applicant has requested DP and confidentiality of certain scientific data and evidence included in their application, as permitted in Article 26 and Article 23 of Retained EU Regulation 2015/2283. An applicant's request for DP and confidentiality can be granted as part of the authorisation, this is subject to a data protection period of 5 years as stated in Retained EU Regulation 2015/2283 – such that only the applicant is able to market this NF during that time, unless a subsequent application is made without reference to the propriety scientific data, or with the agreement of the applicant.

Proposed terms for entry to the list of authorised novel foods

The proposed terms for entry to the list of authorised novel foods are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms and is not liable to have an effect on human health.

Any relevant provisions of retained EU law

FSA/FSS has not identified any relevant provisions of retained EU law that would impact authorisation for the extension of use of this product.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this NF. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

This NF is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex E: RP810 – DHA 550 (application to increase the daily intake of DHA from this source to 1000 mg/day) (extension of use for current authorisation)

Background

This application was submitted as set out in Retained EU Regulation 2015/2283. The application was submitted for an increased level of use for the authorised docosahexaenoic acid (DHA)-rich oil from *Schizochytrium* sp. to obtain the authorisation to use such oils in food supplements up to 1000 mg/day. This application is related to a *Schizochytrium* sp. oil compliant with the specifications laid down in Retained EU Regulation 2017/2470.

The applicant has requested confidentiality of certain information included in their application, as permitted in Article 23 of Retained EU Regulation 2015/2283.

Proposed terms for entry to the list of authorised novel foods

The proposed terms for entry to the list of authorised novel foods are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms and is not liable to have an effect on human health.

The designation of the NF on the labelling of the foodstuffs containing it shall be “Oil from the microalgae *Schizochytrium* sp.”

Any relevant provisions of retained EU law

FSA/FSS has not identified any relevant provisions of retained EU law that would impact authorisation for the extension of use of this product.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons

for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this NF. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

This NF is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex F: RP811 – DHA 550 (application to extend the use of the authorisation to infant and follow-on formula) (extension of use for current authorisation)

Background

This application was submitted as set out in Retained EU Regulation 2015/2283. The application was submitted for an extension of use, and it refers to a *Schizochytrium* sp. oil rich in docosahexaenoic acid (DHA) which is already authorised as a NF. This extension of use is for use in infant and follow-on formula. This application is related to a *Schizochytrium* sp. oil compliant with the specifications laid down in Retained EU Regulation 2017/2470.

The applicant has requested confidentiality of certain information included in their application, as permitted in Article 23 of Retained EU Regulation 2015/2283.

Proposed terms for entry to the list of authorised novel foods

The proposed terms for entry to the list of authorised novel foods are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms and is not liable to have an effect on human health.

DHA is mandatory in infant and follow-on formula under Regulation (EU) 2016/127. Its addition should be in the range of 20 mg/100 kcal minimum to 50 mg/100 kcal maximum. The target population is infants and young children.

It should be noted that manufacturers of infant and follow-on formula who may powder the NF and incorporate it into their formulae shall guarantee that the concentration of DHA meets the requirement of the Regulation. This is also the case if other sources of DHA are used in combination with the NF.

The designation of the NF on the labelling of the foodstuffs containing it shall be “Oil from the microalgae *Schizochytrium* sp.”

Any relevant provisions of retained EU law

FSA/FSS has not identified any relevant provisions of retained EU law that would impact authorisation for the extension of use of this product.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this NF. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

This NF is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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